

21. (New) The bone-tendon-bone graft of claim 19, wherein said dowel has a tapered region.

22. (New) The bone-tendon-bone graft of claim 19 being an allograft.

23. (New) The bone-tendon-bone graft of claim 19 being a xenograft.

24. (New) The bone-tendon-bone graft of claim 23, wherein said xenograft has been processed to minimize the level of antigenic agents or potentially pathogenic agents.

A clean copy of all claims, including the new and amended claims, is attached hereto in Exhibit A.

#### **REMARKS**

Claims 6-13 and 18 have been cancelled pursuant to 37 C.F.R. § 1.144, as required by the Patent Office in the Office Action of 09/11/02.

The amendments to the claims do not add new matter. The amendment to claim 1 recites limitations that more clearly convey what Applicants regard as the instant invention. Support for the amendment to claim 1 is found throughout the specification, including at page 2, lines 10-13 ("the subject invention pertains to a bone-tendon-bone graft useful in orthopedic surgery comprising one or more bone blocks, and a tendon attached to said one or more bone blocks, wherein said one or more bone blocks is pre-shaped into a dowel"). The amendment to claim 17, which merely corrected dependency, was required by the Patent Office. New claim 19, which is directed to "[a] bone-tendon-bone graft suitable for implanting in humans comprising a first bone block and a second bone block naturally interconnected by a tendon, wherein

said first bone block and said second bone block has been preshaped into a dowel,” is supported throughout the specification, including at page 3, lines 25-27 (“Referring to Figure 1, there is shown an embodiment directed to a BTB 100 comprising a first bone block 110 and a second bone block 120 interconnected by a tendon 130, wherein each bone block has been preshaped into dowels”); and at page 2, lines 21-22 (“the subject invention pertains to a method of conducting orthopedic surgery on a **human** . . .”); and at page 4, lines 1-2 (“BTB is preferably isolated from the knee of a donor.”). Claim 20, which is directed to the “bone-tendon-bone graft of claim 19, wherein said dowel has **radius cuts**,” is supported throughout the specification, including at page 4, lines 9-10 (“the dowels are preferentially machined down the length of the bone block to form **radius cuts**.”). [Emphasis added in bold.] Claim 21, which is directed to the “bone-tendon-bone graft of claim 19, wherein said dowel has a **tapered region**,” is supported throughout the specification, including at page 4, line 28 (“the bone blocks are shaped into dowels with **tapered ends**.”); at page 4, line 29 (a proximal **tapered region**) and at page 4, line 30 (a distal **tapered region**). [Emphasis added in bold.] Claims 22 and 23, which recite that the graft is an “allograft” or “xenograft”, respectively, are supported throughout the specification, including at page 8, lines 18-19 (“Those skilled in the art will appreciate that that the graft may be an autograft, allograft, or xenograft.”) Claim 24, which is directed to the “bone-tendon-bone graft of claim 23, wherein said xenograft has been processed to minimize the level of antigenic agents or potentially pathogenic agents,” is supported throughout the specification, including at page 8, lines 19-20 (“Xenograft implants may further require treatments to minimize the level of antigenic agents and/or potentially pathogenic agents present in the graft.”).

Therefore, the amendments to the claims do not add new matter.

#### Claims under Examination

Claims 1, 2, 4, 5, 14, 17 and 19-24 are pending.

### Summary of the Bases for Rejection

Claim 1 is rejected under 35 U.S.C. § 102(b), as being allegedly anticipated by U.S. Patent No. 5,370,662 (Stone).

Claims 2, 4, and 5 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 5,370,662 (Stone) in view of U.S. Patent No. 5,562,669 (McGuire).

The Applicants will address each of these bases for rejection in Sections I-II, respectively, which follow.

#### I. 35 U.S.C. § 102(b)

Claim 1 is rejected under 35 U.S.C. § 102(b), as being allegedly anticipated by U.S. Patent No. 5,370,662 (Stone). In order for a reference to anticipate a claim, the reference must teach every element of the claim. See *Verdegaal Bros. V. Union Oil Co. of California*, 2USPQ2d 1051,1053 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”); and MPEP §2131.

In the present case, claim 1 is drawn to a bone tendon bone graft which is an implantable “**unitary**” structure comprising at least one dowel shaped bone block with a **tendon attached thereto** said at least one bone block, wherein at least one bone block comprises a first end and a second end which are tapered.

The Patent Office contends that Stone “discloses a bone tendon bone graft (10) comprising a **tendon (30)** and a bone block (12) having a first end and a second end (16)” wherein the first and second ends are tapered. [Office Action, page 2 ; emphasis added in bold]. However, referring to Stone at col. 4, lines 36 and 56 reflect that element **30** is a “suture,” *i.e.*, a catgut or thread for attachment to soft tissue, such as a tendon. [See Stone at col. 2, lines 14-16 (“the present invention generally relates to suture anchor assemblies of the type used for securing soft tissue to bone.”)] However, even assuming that the suture is a tendon, Stone does not disclose a **unitary** bone tendon bone graft structure comprising at least one bone block having a **tendon attached thereto** said at least one bone block. Instead, as stated at column 2,

lines 13-27, Stone discloses a suture anchor assembly having an eyelet where, upon surgical implantation, one or more **separate** sutures can be “**receive[d]**” in an eyelet (like a shoestring in a shoe) and secured. As illustrated in Stone at Figures 1-3 and as stated in Stone at column 4, lines 32-25:

In the illustrated embodiment of FIG. 1, the top portion **16** includes an eyelet **18** of sufficient size to **receive** one or more sutures **30**.

[Emphasis added in bold.]

Since Stone does not disclose a bone tendon bone graft that is a “**unitary**” structure (*i.e.*, **integrally attached**) comprising at least one bone block with a tendon attached thereto said at least one bone block, Applicants respectfully submit that the Patent Office has not met the burden of establishing a *prima facie* case of anticipation.

Finally, there is no disclosure anywhere in Stone that the screw-like anchor (“cylindrical member”) that is disclosed therein is “bone.” Hence, even if a tendon were attached to it, it could not comprise a bone-tendon combination as recited by claim 1. Specifically, without describing the material used to make the bone anchor (“cylindrical member”), Stone describes the preferred material for making it as a synthetic (non-bone) material:

**Preferably**, the cylindrical member 12 is manufactured from **stainless steel, titanium** or some other **durable, non-degradable, biocompatible material**. **Alternatively**, the cylindrical member 12 may be manufactured from a **non-biocompatible material**, but **coated** with a biocompatible substance prior to insertion into a patient.

[Stone at col. 4, lines 3-8; emphasis added in bold.]

Thus, Stone’s failure to disclose that his screw-like bone anchors (“cylindrical members”) are made of bone, is yet a third separate and distinct reason for finding that Stone is not anticipatory of the bone-tendon-bone graft of claim 1 of the Applicant’s invention.

For all these reasons, Applicants respectfully request withdrawal of this basis for rejection.

## II. 35 U.S.C. § 103(a)

Claims 2, 4, and 5 are rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over U.S. Patent No. 5,370,662 (Stone) in view of U.S. Patent No. 5,562,669 (McGuire). Dependent claim 2 is drawn to the bone tendon bone graft of claim 1, wherein said bone tendon bone graft comprises one bone block, and wherein said tendon is derived from an Achilles tendon, patellar tendon, or quadriceps tendon of a donor. Dependent claims 4 and 5 are drawn to the bone tendon bone graft of claim 2, wherein said one bone block comprises a groove sufficient to accommodate a fixation screw or comprises at least one graft manipulation hole.

One of the criteria that must be met in order to establish a *prima facie* case of obviousness is that the prior art references must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination must be found in the prior art. See *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991) and MPEP § 2142, 2143, and 2143.03. The Applicants respectfully submit that neither U.S. Patent No. 5,370,662 (Stone) nor U.S. Patent No. 5,562,669 (McGuire), either individually or in combination, teaches or suggests the limitations of independent claim 1 and dependent claims 2, 4, and 5.

The Patent Office admits that Stone “does not disclose a tendon derived from a patellar tendon.” [Office Action, page 3]. Nevertheless, the Patent Office asserts that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ligament of Stone with the natural patellar ligament of McGuire in order to increase the biocompatibility of the implant. The Applicants respectfully disagree.

As discussed in Section I above, Stone does not teach or suggest an implantable “unitary” bone-tendon-bone graft structure comprising at least one bone block having a tendon attached thereto said at least one bone block. Rather, Stone

teaches a device for attaching soft tissue to bone that is composed of at least two **separate** components that are brought together at an eyelet 18, like a shoe and a shoestring. Similarly, McGuire does not teach or suggest an implantable, unitary bone tendon bone graft structure comprising at least one bone block having a tendon attached thereto said at least one bone block. Instead, McGuire discloses bone plugs having parallel grooves or holes for attaching the **separate** tendons (such as by sutures) to the bone plug. As illustrated in Figures 4a and 4b of McGuire and as stated in McGuire at column 4, lines 10-22:

Whatever bone plug **25** is used, two longitudinal substantially parallel grooves **50** are drilled on opposite sides of each bone plug. The grooves provide a recess in which the semitendinosus tendon **20** and gracilis **21** can be seated. It is also advantageous to provide **suture holes 27** through the bone plug for **attaching the tendon to the plug**.

[Emphasis added in bold.]

Because neither Stone nor McGuire, either individually or in combination, teaches or suggests the "unitary" limitation of independent claim 1, or of claims 2, 4, and 5 which depend therefrom, Applicants respectfully submit that the Patent Office has not met the burden of establishing a *prima facie* case of obviousness. Therefore, Applicants respectfully request the withdrawal of this basis for rejection.

### CONCLUSION

Claims 1-2, 4-14 and 17-18 are pending. Claim 14 has been allowed. Claim 17, is allowable, but was objected to for being dependent upon a cancelled claim. Claims 1-2 and 4-5 stand rejected. Claims 6-13 and 18 have been cancelled for being directed to a non-elected invention. Claims 19-24 have been added by amendment herein. Accordingly, claims 1-2, 4-5, 14, 17 and 19-24 (if the latter are entered) are pending.

In view of the amendments and arguments provided herein, all bases for rejection of claim 1 under 35 U.S.C. § 102(b) for alleged anticipation have been

rebutted. In view of the amendments and arguments provided herein, all bases for rejecting claims 2, 4, and 5 under 35 U.S.C. § 103(a) have been rebutted.

Claims 1- 2, 4-5, 14, 17 and 19-24 are in condition for allowance.

Respectfully submitted,

**McANDREWS, HELD & MALLOY, LTD.**

By:



Donald J. Pochopien

Registration No. 32,167

Attorney for Applicants

500 West Madison Street

34th Floor

Chicago, Illinois 60661

(312) 775-8133

Date: November 11, 2002

J:\open\Djp\Regeneration Technologies\USPTO\13921US02\ Amndt and Response.doc